

§ 113.205

test is considered inconclusive and may be repeated: *Provided*, That, if at least 80 percent of the vaccinates do not remain well and free of detectable virus in the feces, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66786, Dec. 26, 1991; 60 FR 14361, Mar. 17, 1995]

§ 113.205 Newcastle Disease Vaccine, Killed Virus.

Newcastle Disease Vaccine (Killed Virus) shall be prepared from virus-bearing tissues or fluids obtained from embryonated chicken eggs or cell cultures. With the exception of § 113.200(c)(2)(iii), each serial shall meet the applicable general requirements prescribed in § 113.200 and special requirements prescribed in this section. A serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety test*. The prechallenge part of the potency test in paragraph (b) of this section shall constitute a safety test. If unfavorable reactions attributable to the product occur in any of the vaccinates, the serial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial shall be declared unsatisfactory.

(b) *Potency test*. A vaccination-challenge test shall be conducted using susceptible chickens 2 to 6 weeks of age at time of vaccination, properly identified and obtained from the same source and hatch.

(1) Ten or more chickens shall be vaccinated as recommended on the label and kept isolated under observation for at least 14 days.

(2) After at least 14 days post-vaccination, the vaccinates and at least 10 unvaccinated chickens that have been kept isolated as controls shall be challenged with a virulent strain of Newcastle disease virus supplied by or approved by Veterinary Services and the vaccinates observed each day for 14 days.

(3) If at least 90 percent of the controls do not show typical signs of Newcastle disease or die, the test is inconclusive and may be repeated. If at least 90 percent of the vaccinates do not re-

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main normal, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66786, Dec. 26, 1991]

§ 113.206 Wart Vaccine, Killed Virus.

Wart Vaccine, Killed Virus, shall be prepared from virus-bearing epidermal tumors (warts) obtained from a bovine. Each serial shall meet the requirements prescribed in this section and any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity*. Final container samples of completed product shall meet the requirements for purity as prescribed in § 113.200 (c)(1) and (3).

(b) *Safety*. Bulk or final container samples of completed product shall meet the requirements for safety as prescribed in §§ 113.33(b) and 113.38.

(c) *Formaldehyde content*. Bulk or final container samples of completed product shall meet the requirements for formaldehyde content as prescribed in § 113.200(f).

(d) *Potency and efficacy*. The efficacy of wart vaccine has been demonstrated to the satisfaction of Veterinary Services as being a valuable biological product. The inherent nature of the product precludes the possible development of serial to serial potency tests and none is required: *Provided*, That,

(1) The vaccine shall be a tissue extract representing at least 10 percent weight to volume suspension of wart tissue; and

(2) The vaccine shall be limited to use in the prevention of warts in cattle. Labeling recommendations shall be in accordance with § 112.7(i).

[40 FR 14084, Mar. 28, 1975, as amended at 40 FR 23989, June 4, 1975; 40 FR 30803, July 23, 1975. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66786, Dec. 26, 1991]

§ 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in § 113.200, except those in § 113.200(d). Any serial or